

PU3616US2  
10/637,190

### REMARKS

Claims 16 and 36 are pending in this application.

#### Rejection under 35 USC 112, first paragraph (enablement)

The Office Action states that the claims are rejected under 35 USC s.112, first paragraph, "because the specification while being enabling for the treatment of atherosclerosis does not reasonable provide enablement for the treatment of all disease mediated by modified lipid levels." (Office Action , page 3-4). Applicants respectfully traverse this rejection.

The Examiner's position as stated in the Office Action is that the specification does not enable the treatment of "all disease mediated by modified lipid levels." However, the present claims are directed to a method of decreasing serum triglycerides in a mammal by administering certain compounds. It is accepted that there must be a reasonable correlation between the scope of what is claimed and the scope of enablement provided by appellants' specification to the person of ordinary skill in the art. In re Vaeck, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991), In re Fisher, 166 USPQ 18, 24 (CCPA, 1970). In the present case, what is claimed is a method of lowering serum triglycerides.

The specification does mention certain diseases, some of which are associated with modified lipid levels (see, e.g., page 7, lines 21-25; page 18, lines 18-20; page 28, lines 2-3). However, in view of the claim language, Applicants submit that the present patentability analysis has improperly imported limitations from the specification (treatment of disease) into the claims. It is a general principle of claim construction that limitations found only in the specification of a patent application should not be imported or read into a claim. See In re Priest 199 USPQ 11, 15 (CCPA 1978).

Applicants submit that the claims have been improperly construed. The present claims recite a method of altering a physiological parameter (serum triglyceride levels), and do not claim a method of alleviating or curing disease. The present rejection appears to be based on a concern that the claimed method would not be efficacious for treating all the disease states mentioned in the specification, and/or all disease states associated with

PU3616US2  
10/637,190

altered serum triglyceride levels. Applicants respectfully submit that this concern is misplaced in view of the actual claim language. As the court observed in In re Brana 34 USPQ2d 1436, 1442 (Fed. Cir. 1995), it is possible that the examiner "confuses the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption."

The Office Action states that the enablement rejection would be overcome by amending the claims to include only the method of lowering serum triglycerides for the treatment of atherosclerosis (Office Action page 7). However, as stated in MPEP 2164, "(t)he invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application" (underlining added). As stated in MPEP 2164.01(a), a conclusion of lack of enablement means that, based on the evidence regarding each of the factors discussed in In re Wands, the specification at the time the application was filed, "would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation." (Citing *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

In the present case, the Examiner has not questioned the ability of one skilled in the art to make the compounds recited in the claims, nor the ability to reduce serum triglycerides in a mammal by administration of such compounds. Neither has the Examiner has questioned the utility of such a claimed method.

Applicants submit that the Examiner has not established that any unpredictability in this art extends to the claimed methods. Withdrawal of the present rejection is respectfully requested.

Rejection under 35 USC 112, second paragraph (indefiniteness)


Claim 16 stands rejected as indefinite for reciting "GW4064". This claim has been amended according to the Examiner's suggestion, to include the chemical structure of GW4064. This amendment is supported by the specification as filed, e.g., at page 7.

PU3616US2  
10/637,190

Conclusion

In view of the above, Applicants respectfully submit that the present application is in condition for allowance.

Respectfully submitted,



Virginia C. Bennett  
Attorney of Record  
Registration No. 37,092

Date: July 19, 2004  
GlaxoSmithKline  
5 Moore Drive, P.O. Box 13398  
Research Triangle Park, NC 27709  
Telephone: (919) 483-1012  
Facsimile: (919) 483-7988